

Appl. No. : **09/892,900**
Filed : **June 26, 2001**

REMARKS

In response to the Office Action mailed October 21, 2003, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments. As a result of the amendments listed above, Claims 14-27 remain pending, Claims 18, 20-22 and 25-27 having been withdrawn without prejudice as directed to a non-elected invention. No claims have been amended.

Non-Entry Of Amendment To The Specification

In paragraph 2 of the outstanding Office Action, the Examiner has indicated that the amendment to page 2, line 31 in the Amendment filed July 29, 2003 has not been entered because the amendment did not comply with 37 C.F.R. § 1.121. Specifically, the added matter was not underlined and the deleted matter was not shown as struck through.

Applicant respectfully submits that the subject amendment was intended to delete the existing paragraph at page 2, line 30 and insert an entirely new paragraph in its place. This amendment was intended to address the Examiner's objection to the Summary of the Invention section, in the Action mailed January 30, 2003, as not being commensurate with the claimed subject matter.

37 C.F.R. § 1.121(iii) provides that the full text of any added paragraph should be presented without underlining. 37 C.F.R. § 1.121(iv) provides that the text of a paragraph to be deleted must not be presented with strike-through or placed within double brackets. Applicant has reiterated the request to delete the paragraph beginning at page 2, line 31 and add the new paragraph in the present amendment. Entry of this amendment is respectfully requested.

Priority Claim

In the outstanding Office Action, the Examiner indicated that the amended priority claim, filed July 29, 2003, was not entered because the reference was not filed within the later of four months from the filing date of the application or sixteen months from the earliest effective filing date. Applicant respectfully submits that the present application was amended to include a reference to prior-filed applications ("the original reference") by a preliminary amendment filed with the present application. Thus, the original reference was filed within four months of the filing date of the present application. However, the original reference inadvertently omitted one application (i.e., the 08/008,790 application) from the family of related applications.

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The present application was appropriately scheduled for publication based on the originally submitted priority information. Applicants further note that the earliest effective filing date in the original reference is the same as the earliest effective filing date in the amended reference. Thus, because the appropriate information for the purpose of scheduling publication was timely presented, and acknowledged by the Office, no petition or petition fee should be required to enter the amendment to the priority claim in the instant application. Nonetheless, Applicants have filed herewith a Petition Under 37 C.F.R. § 1.78(A)(6) to accept an unintentionally delayed priority claim. If necessary, the Petition also authorizes the Office to charge the petition fee to Deposit Account No. 11-1410. Accordingly, entry of the amendment to the priority claim filed July 29, 2003 is respectfully requested.

Response To Request To Delete Subject Matter Not Germane To The Present Invention

In paragraph 5 of the outstanding Office Action, the Examiner states that the present application is a divisional application because it claims only subject matter disclosed in an earlier application. The Examiner also states that the application should set forth only that portion of the earlier disclosure that is germane to the invention claimed in the present application.

In response, Applicants respectfully submit that the Examiner has provided no authority for such a request. Applicants respectfully submit that no basis exists for such a request in current law or procedure. However, in response to the previous Office Action, Applicants amended the priority claim to recite that the present application is a divisional of parent application 08/876,180, rather than a continuation, as originally recited.

Objections To The Description

In the outstanding Office Action, the Examiner objects to the Summary of the Invention section of the present application because the description of the claimed invention is not commensurate with the scope of the claims. Applicants respectfully submit that the application has been amended herein such that the description of the claimed invention is commensurate with the scope of the claims.

In addition, Applicants have also amended the present application to address the Examiner's other objections in paragraph 8 of the outstanding Office Action. Thus, Applicants respectfully request reconsideration and withdrawal of the objections in paragraph 8 of the outstanding Office Action.

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Rake et al. Is Not Prior Art To The Present Application

Claims 14-17, 19 and 23-24 presently stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,911,716 to Rake et al. Applicants respectfully submit that Rake et al. is not prior art to the present application and request reconsideration and withdrawal of the present rejection.

As set forth above, and in the previous amendment, the priority claim as submitted in the preliminary amendment filed June 26, 2001 inadvertently omitted the grandparent to the present application. The priority claim has been amended to include the grandparent application and, as a result, the effective filing date of the present application is the same as the filing date of Rake et al., i.e., January 24, 1992. In addition, for at least the reasons set forth above, Applicants submit that the amendment to the priority claim should be entered without a petition under 37 C.F.R. § 1.78(a)(3) or (a)(6). Accordingly, Rake et al. is not prior art to the present application under 35 U.S.C. § 102(e) and Applicants respectfully request reconsideration and withdrawal of the present rejection of Claims 14-17, 19 and 23-24 in light of Rake et al.

Bessesen Does Not Anticipate Claims 14-17, 19 and 23

Claims 14-17, 19 and 23 presently stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bessesen. Applicants respectfully submit that the Bessesen reference does not anticipate Claims 14-17, 19 and 23 and request reconsideration and withdrawal of the present rejection.

As set forth in the previous amendment, the Bessesen reference discloses a syringe including a piston that is configured to apply a pressure to a fluid within a reservoir defined by a barrel of the syringe. The surface of the piston that faces the fluid reservoir is hemispherical in shape and an end surface of the barrel is conical in shape. Thus, if the piston is in a position minimizing the volume of the reservoir, the hemispherical surface of the piston and the conical surface of the barrel would contact one another only along a contact radius positioned between a central axis of the reservoir and an outer periphery of the reservoir.

As argued in the previous amendment, such a construction results in a residual amount of fluid being retained within the reservoir when the piston is fully extended into the barrel of the syringe. While volume of retained fluid may be acceptable in a syringe, it would be highly undesirable in an infusion pump due, at least in part, to the significantly larger volume of fluid typically dispensed from an infusion pump versus the volume dispensed from a syringe. In

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addition, in the context of an infusion pump, retained fluid within the reservoir would decrease the length of the infusion cycle, or require a larger reservoir to compensate for the retained volume of fluid. Either condition would be highly undesirable in an infusion pump application.

In contrast, Claim 14 recites an infusion pump including, among other limitations, a first shell defining a non-planar interior surface and a platen defining a non-planar surface complementary to the surface of the first shell. The surfaces of the first shell and the platen are configured to receive a fluid delivery bag therebetween. The platen is biased to compress the fluid delivery bag between the surfaces of the first shell and platen.

Such a construction, as described in the present specification, advantageously permits the infusion pump to substantially completely deliver the fluid within the fluid delivery bag. See page 14, lines 9-24 for example. Thus, with complementary surface configurations, the duration of the fluid delivery cycle is optimized and waste of medicinal fluid is minimized. Furthermore, Applicants note that the claims are not to be interpreted in a vacuum, but are to be interpreted in light of the specification. M.P.E.P. 2111.01. Thus, one of skill in the art would recognize that to be complementary as recited by the claims, the surfaces of the platen and the first shell require greater conformance between their shapes than that necessary to produce a simple contact radius, or circular line of contact, as would occur in the construction of the Bessesen reference. Accordingly, Applicants respectfully submit that the Bessesen reference does not disclose the necessary "complementary" surfaces to anticipate Claim 14.

In addition, as set forth in the previous amendment, it is respectfully submitted that the piston of the Bessesen reference does not anticipate the platen limitation of Claim 14. As discussed in the present specification, the provision of a platen defining a non-planar surface for compressing the fluid delivery bag permits a relative constant contact area between the platen and the bag during the fluid delivery cycle. If the platen were replaced with a hemispherical piston of the Bessesen reference, the contact area between the piston and a fluid delivery bag would sharply increase over the initial portion of the fluid delivery cycle.

The Examiner states that a platen, as claimed, is not a plate-like member because the claimed platen includes a non-planar surface. Applicants respectfully submit that the dictionary definition of "platen" is a plate-like member, especially one that exerts pressure. In addition, the movable member of the infusion pump that exerts pressure on the fluid within the pump is described throughout the specification as a "platen". Thus, the claimed platen is a plate-like

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member that defines a non-planar surface. Multiple embodiments of the claimed platen are described within the specification and shown in the figures. Accordingly, Applicants submit that the hemispherical piston of the Bessesen is not a platen, as the term would be interpreted by one of skill in the art in light of the present disclosure.

For at least the reasons presented above, Applicants respectfully submit that Claim 14 is not anticipated by the Bessesen reference. Independent Claims 19 and 23 include limitations similar to the limitations of Claim 14 discussed above and are allowable at least for essentially the same reasons. The remaining dependent claims are allowable, not only because they depend from allowable independent claims, but on their own merit as well. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection of Claims 14-17, 19 and 23.

Claims 14-15, 17, 19 and 23-24 Are Patentable Over The Applied Combination Of May/Dorman/Jassawalla et al.

Claims 14-15, 17, 19 and 23-24 presently stand rejected under 35 U.S.C. § 103(a) as being unpatentable over May in view of Dorman et al. and Jassawalla et al.. Applicants respectfully submit that Claims 14-15, 17, 19 and 23-24 are patentable over the applied combination and request reconsideration and withdrawal of the present rejection.

The May reference discloses a combined wound irrigator and evacuator device. The device of May includes a housing having an interior space divided into an irrigator section and an evacuator section by a diaphragm or, alternatively, by a piston. The volumes of the irrigator section and the evacuator section are inversely affected by movement of the diaphragm (or piston). That is, in operation, the diaphragm is biased to reduce a volume of the irrigator section to expel an irrigation fluid therefrom while the volume of the evacuator section is increased to draw fluid from the wound into the evacuator section. The May reference does not, however, disclose non-planar complementary surfaces acting to compress a fluid delivery bag.

The Examiner states that it would be obvious to one of skill in the art to combine the combined irrigator/evacuator of the May reference with the infusion pump constructions of the Dorman et al. and Jassawalla et al. references to arrive at the constructions recited in Claims 14-15, 17, 19 and 23-24. The Dorman et al. reference discloses an infusion pump utilizing a plurality of diaphragm springs to provide a biasing force to expel fluid from the pump. The Jassawalla et al. reference discloses an infusion pump including a motor-driven, collapsible

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bellows arrangement to expel fluid from the pump. Each of the Dorman et al. and Jassawalla et al. references disclose infusion pumps with opposing non-planar surfaces that are similar in shape to one another.

Applicants respectfully reiterate that any motivation for combining these references, as suggested by the Examiner, is the result of hindsight resulting from the teaching of the present application. The Examiner states that a motivation to combine the references results from the recognition that the constructions of the Dorman et al. and Jassawalla et al. references would provide more complete expelling of fluid and the desire of the May reference to cost efficiently expel fluids. However, as explained in the previous amendment, it does not appear that the expulsion of fluid from the combined irrigator/evacuator disclosed in the May reference would be less than complete because the device includes flat opposing surfaces for compressing the fluid bag therebetween. There is no indication that the opposing surfaces would be prevented from completely compressing the fluid bag and, therefore, no motivation exists to modify the May reference with features of either the Dorman et al. or Jassawalla et al. references under the motivation stated by the Examiner.

For at least the reasons presented above and in the previous amendment, Applicants respectfully submit that the applied combination of May/Dorman et al./Jassawalla et al. is improper. Thus, Applicants respectfully request reconsideration and withdrawal of the present rejection of Claims 14-15, 17, 19 and 23-24.

A Terminal Disclaimer Is Filed Herewith To Obviate The Double Patenting Rejection

Claims 14-17, 19, 23 and 24 presently stand rejected under the judicially created doctrine of obviousness-type double patenting over Claim 1-4 of U.S. Patent No. 5,911,716. In response, Applicant has filed a terminal disclaimer herewith, in accordance with 37 C.F.R. § 1.321(c), to obviate the rejection. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present rejection.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims and specification. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped

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issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, Curtiss C. Dosier at the number provided below, to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: APRIL 20, 2004

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